K083107

510(k) Summary
Modified DePuy NeuFlex PIP Finger Prosthesis

Applicant / Sponsor:	DePuy Orthopaedics, Inc. 700 Orthopaedic Drive Warsaw, IN 46581
Contact Person:	Janet G. Johnson, RAC Manager Regulatory Affairs (574) 372-7469
Proprietary Name:	DePuy NeuFlex PIP Finger
Common Name:	Finger Joint Prosthesis
Classification:	888.3230 Finger joint, polymer, constrained prosthesis
Product Code:	87 KYJ
Substantial Equivalence	DePuy NeuFlex PIP Finger (K001922) NeuFlex MCP Finger Prosthesis (K970544) Dow Corning Wright Swanson Finger Implant

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Indications for Use:

The Modified DePuy NeuFlex PIP Finger Prosthesis is indicated for cementless replacement of the proximal interphalangeal (PIP) joints of the finger where disabled by rheumatoid, degenerative or traumatic arthritis.

Device Description:

The Modified DePuy NeuFlex PIP Finger Prosthesis is a flexible, one-piece silicone implant designed to be implanted across the PIP joint. The proximal and distal stems of the prosthesis form an angle, which mimics the approximate position of the joint when the hand is relaxed. This angle is the most obvious difference between the Modified DePuy NeuFlex PIP Finger Prosthesis and other commercially available silicone finger joint prostheses, which have an unflexed, neutral angle of 0°.

Summary of Technologies/Substantial Equivalence:

The Modified DePuy NeuFlex PIP Finger Prosthesis has the same indications for use, design, materials, sterilization and packaging to the current DePuy NeuFlex PIP Finger (K001922), NeuFlex MCP Finger Prosthesis (K970544) and the Dow Corning Wright Swanson Finger Implant.

The determination of substantial equivalence for this device was based on a detailed device description, product testing and conformance performance standards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DePuy Orthopaedics Inc.
% Ms. Janet Johnson
Manager, Regulatory Affairs
P.O. Box 988
700 Orthopaedic Drive
Warsaw, Indiana 46581

FEB - 9 2009

Re: K083107
Trade/Device Name: DePuy NeuFlex PIP Finger
Regulation Number: 21 CFR 888.3230
Regulation Name: Finger joint polymer constrained prosthesis
Regulatory Class: II
Product Code: KYJ
Dated: January 14, 2009
Received: January 15, 2009

Dear Ms. Johnson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known) K083107

Device Name DePuy NeuFlex PIP Finger

Indications for Use:

The DePuy NeuFlex PIP Finger Prosthesis is indicated for cementless replacement of the proximal interphalangeal (PIP) joints of the finger where disabled by rheumatoid, degenerative or traumatic arthritis.

Prescription Use X OR Over-the-Counter Use
(Per 21 CFR 801 Subpart D) (Per 21 CFR 801 Subpart C)

(Please do not write below this line - Continue on another page if necessary)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K083107